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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,770	12/29/2000	Kuber T. Sampath	00960-520PRO	7664
28120	7590	06/01/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/581,770	SAMPATH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 20,22-24,26,31 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20, 22-24, 26, 31, and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed on March 15, 2004 has been entered in full. Claims 20 and 31 have been amended. Claims 21, 25, 27-30, 32, 33, and 35-38 have been canceled. Claims 20, 22-24, 26, 31, and 34 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Withdrawn Objections and/or Rejections**

Applicants' cancellation of claims 21, 25, 27, 33, and 38 has made all the rejections and objections set forth in the previous office action mailed on December 17, 2003 moot.

The rejection of claims 20-25, 27, 31, 33, and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,531,445 B1, as set forth at pages 5-6 in the previous office action mailed on December 17, 2003 has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 20-27, 31, 33, and 34 under 35 U.S.C. §112, 1<sup>st</sup> paragraph for written description, as set forth at pages 8-9 in the previous office action mailed on December 17, 2003 has been withdrawn in view of Applicants' amendment to the claims.

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The rejection of claims 20-27, 31, 33, 34, and 38 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as set forth at pages 9-10 in the previous office action mailed on December 17, 2003 has been withdrawn in view of Applicants' amendment to the claims and argument.

The rejection of claims 20-24, 27, 31, 33, and 38 under 35 U.S.C. §102 (b) as being anticipated by Rueger et al., as set forth at pages 10-11 in the previous office action mailed on December 17, has been withdrawn in view of Applicants' amendment to the claims.

### **III. Sequence Compliance**

The requirement for sequence compliance, as set forth at pages 3-4 in the previous office action mailed on December 17, 2003, has been withdrawn in view of Applicants' amendment to the specification and claims.

### **IV. Claim Rejections under Nonstatutory Obviousness-Type Double Patenting**

The rejection of claims 20, 22-24, 26, 31, and 34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1, as set forth at pages 4-5 in the previous office action mailed on December 17, 2003, is maintained.

Applicants, citing MPEP, argue that the nonobviousness requirement of 35 U.S.C. 103 is similarly required in a double patenting rejection of the obviousness type. Applicants submit that the Examiner has failed to (a) make clear all the differences between the patented and the subject claims; (b) make clear why a person of ordinary

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skill in the art would conclude that the claimed invention is an obvious variation of the claimed invention; and (c) show how the cited references teach or suggest all the limitations of the instant claims. Applicants further submit that the Examiner has failed to clearly explain the alleged species to genus relationship between the patented and the instant claims.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the Examiner notes that the nonstatutory obviousness-type double patenting rejection set forth in the previous office action is based upon **anticipation analysis**, not **obviousness analysis**. Thus, the analysis under nonobviousness requirement of 35 U.S.C. 103 is not required. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Secondly, the previous office action has stated that although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 20, 22-24, 26, 31, and 34 are generic to all that is recited in claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1. That is, claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1 falls entirely within the scope of instant claims 20, 22-24, 26, 31, and 34, or in other words, claims 20, 22-24, 26, 31, and 34 are anticipated by claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1. Specifically, treatment of chronic renal

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failure or a renal condition recited in claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1 is encompassed by the instant claims 20, 22-24, 26, 31, and 34 that recite restoring cellular phenotype in a subject's cell (a lung cell, a heart cell, a blood vessel, a stomach cell, a muscle cell, a renal cell or an intestinal cell) affected by disease, damage or age.

#### **V. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Scope of Enablement)**

The rejection of claims 20, 22-24, 26, 31, and 34 under 35 U.S.C. §112, 1<sup>st</sup> paragraph, as set forth at pages 6-8 in the previous office action mailed on December 17, 2003, is maintained.

Applicants argue that the claims recites, in part, "methods for restoring cellular phenotype in a subject's cell affected by disease, damage, or age". For example, a medial collateral ligament cell affected by advanced age may secrete reduced levels of aggrecan. Administration of OP-1 can increase the levels of aggrecan in a cell, and thus restore a cellular phenotype.

Applicants' argument has been fully considered, but is not deemed to be persuasive because while encompassing the example referred by Applicants, the instant claims are far broader than the referred example, as stated in the previous office action (page 7). If the instant claims were drawn to the methods referred in the example, the invention would be enabled. However, it is not the case here.

Applicants argue that Applicants have amended claims 20 and 31 to contain the features previously recited in claims 21, 27, and 38, and to recite certain types of cells used by the invention. Accordingly, the amended claims, and their dependent claims,

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used by the invention. Accordingly, the amended claims, and their dependent claims, are enabled.

Applicant's argument has been fully considered, but is not deemed to be persuasive because claims 21, 27, and 38 were previously rejected (see pages 6-8) and recitation of the limitations of these claims do not overcome the scope of enablement rejection set forth in the previous office action. While limiting to certain cell types, the scope of the invention is still unusually broad; the amended claims still recite the generic term "restoring the cellular phenotype" in the subject's cell. It is noted that Applicants have not fully addressed the issues raised in the previous office action (the middle of page 7). Furthermore, the scope of pathways is still broad; the pathway is not specified. The claims still recite a genus of morphogens with 60% or 70% amino acid sequence identity to the C-terminal seven cysteine domain of human OP-1 (amino acid residues 330-431 of SEQ ID NO: 8), without a specific functional limitation. Since the instant specification fails to disclose the conservative regions that are critical to the structure and function of the genus claimed and the sites at which variability may be tolerated or the sufficient guidance and working examples on the genus of morphogens, an artisan would not be able to make and use such a huge genus of morphogens without undue experimentation.

#### **VI. Claim Rejections under 35 USC § 102 (b)**

The rejection of claims 20, 22-24, 26, 31, and 34 under 35 U.S.C. §102 (b) as being anticipated by Kuberasampath et al., as set forth at pages 11-12 in the previous office action mailed on December 17, is maintained.

Applicants argue that the amended claims recite specific cell types, i.e., lung cells, heart cells, blood vessel cells, renal cells, stomach cells and intestinal cells, but do not recite hepatocytes. This has been fully considered, but is not deemed to be persuasive because Kuberasampath et al. not only teach the use of morphogens to maintain liver function in a mammal, but also teach treatment of transplant tissues, e.g., liver, lung, kidney, pancreas, heart, etc., to provide a cytoprotective effect to the tissue (line 17-23 of page 18). Kuberasampath et al. further teach the expression of OP-1 in kidney-related tissue, brain, heart, lung tissues (lines 24-27 of page 91). Thus, the reference of Kuberasampath et al. still meets the limitations of the amended claims.

#### **VII. Claim Objections—Minor Informalities**

Claims 20, 22-24, 26, 31, and 34 are objected to because they recite non-elected subject matter (non-elected species).

Appropriate correction is required.

#### **VIII. Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

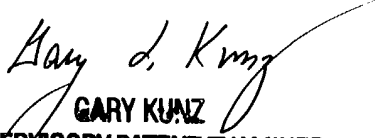
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Gary.Kunz@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Ruixiang Li, Ph.D.  
Examiner  
May 24, 2004

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
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